U.S. Department of Justice

United States Attorney
Eastern District of New York

271 Cadman Plaza East
Brooklyn, New York 11201

August 9, 2022

By ECF
Honorable Steven L. Tiscione
United States Magistrate Judge
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

Re: *United States ex rel. Omni Healthcare, Inc. v. McKesson,*
Civil Action No. 12-CV-6440 (NG) (ST)

Dear Judge Tiscione:

This Office represents non-party Food and Drug Administration ("FDA") and respectfully submits this letter to confirm that, per the Court's recent Order, FDA has submitted for *in camera* review the documents in Document Groups 1 and 7-10 (as described in the Jungman Declaration submitted with FDA's opposition to Defendant McKesson's June 9, 2022 letter-motion to compel (the "Motion") (Dkt. No. 194)). Defendant's claimed need for this privileged material must be viewed in relation to the availability of material on the same subject matter produced through FDA's much larger document production and links to other publicly available material.[1] We believe the following may be helpful to the Court in considering Defendant's purported need for a relatively small set of privileged documents:

- As discussed in FDA's opposition to McKesson's Motion, Dkt. No. 206, and during the July 29, 2022 hearing on the Motion, FDA has produced tens of thousands of pages of documents to McKesson, including nearly 2,000 FDA emails and attachments, over 100 inspectional reports, and over 1,700 pages of documents previously submitted to Congress relating to the New England Compounding Center.[2] These documents, along with public documents such as Congressional testimony, FDA warning letters and other enforcement-related documents, FDA regulations, and FDA manuals and guidelines, collectively illustrate, among other things, a variety of fact patterns presented to FDA

[1] *See Sec. & Exch. Comm'n v. Ripple Labs, Inc.*, No. 20CV10832ATSN, 2022 WL 123590, at *9 (S.D.N.Y. Jan. 13, 2022) ("[T]he availability of more directly relevant information . . . will weigh against disclosure." (citation omitted)).

[2] The New England Compounding Center had distributed a compounded drug that was associated with a 2012 fungal meningitis outbreak which resulted in 51 deaths and over 730 people sickened in 20 states. *See* Jungman Declaration ¶ 10.

regarding compounding and repackaging, as well as FDA policy decisions and other actions taken in response to those fact patterns.

- Additionally, the Markey Report, to which the document in Document Group 1 relates, is a public document which can be found using the following link:

  https://www.markey.senate.gov//imo/media/doc/10-29-12%20Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL.pdf

Respectfully submitted,

BREON PEACE
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